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Serial No.: 09/698,412

Confirmation No.: 5638

Filed: 27 October 2000

For: AUTOMATED RESPIRATOR FIT TESTING METHOD AND SYSTEM**Remarks**

The Office Action mailed 14 August 2003 has been received and reviewed. Claims 12 and 31 have been amended, leaving claims 1-39 pending. Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §103 Rejections**Burstroem in view of Pasternack**

The Examiner rejected claims 1-22 and 24-36 under 35 U.S.C. §103(a) as being unpatentable over Burstroem (FOA Report C40208-C1(C2)) in view of Pasternack (U.S. Patent No. DE 26 52 136 B1). Applicants respectfully disagree with this rejection.

To assist with analysis of this rejection Applicants have obtained a translation of Burstroem and are submitting a copy of same (and a PTO-1449 form listing the original reference and its translation).

On a general note, the discussions provided with respect to this rejection contain many different assertions with respect to various specific claims. Applicants note, however, that many of these assertions are based on broad conclusory statements such as, e.g., "a matter of mere obvious and routine choice of design," "the duplication of a known part for a known purpose," "the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art," etc. To the extent such statements are not specifically addressed below, Applicants respectfully traverse all and any such assertions and request that the Examiner provide some basis in the art for such currently unsupported or unspecified assertions.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation in the references themselves or the knowledge generally available to one skilled in the art to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the references must teach or suggest all the claim limitations (M.P.E.P §2143).

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Burstroem teaches a tent adapted for use during qualitative fit testing of respirators using tear gas as a testing agent. Because it is not a sealed environment, the concentration of the tear gas within the tent decreases over time as illustrated in Figures 4-7. This leakage, however, is not considered to be a problem because the testing is performed outdoors where the tear gas dissipates rapidly.

In contrast, Pasternack teaches a system for quantitative fit testing of one respirator on a single individual. As noted in the translation of Pasternack: "The inside space of the mask between the breathing protection mask and the covered parts of the head of the carrier is connected through the connection line to the test gas measuring device 15." See Pasternack Translation, p. 5. In other words, the testing system of Pasternack is not qualitative, but quantitative. In addition, the measurements of contamination inside the mask require comparison to a baseline concentration delivered to the measuring device 15. "Here [in the measuring device 15] the test gas concentration on the inside of the mask is measured after induction from the mixing and regulating device 10 through the connection 16. This way the leakage in and around the mask is determined." *Id.*

Applicants respectfully submit that the combination of Burstroem in view of Pasternack does not meet the requirements for a *prima facie* case of obviousness because the cited references do not support the asserted suggestion/motivation to combine the references, i.e., "to insure optimal test aerosol was delivered to the test station." If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984) (*cited by* MPEP § 2143.01, pp. 2100-127 (8th Ed., Rev. 1, Feb. 2003)).

Modifying Burstroem in the proposed manner would render the device taught by Burstroem unsatisfactory for its intended purpose, thus negating the asserted motivation or suggestion required for a *prima facie* case of obviousness. At a basic level, modification of Burstroem using the teachings of Pasternack would require a shift from qualitative fit testing to quantitative fit testing. The Office Action provides no reasoning or discussion as to why one of

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ordinary skill in the art would do so. The resulting test apparatus would become complicated to manage and time consuming to use as each individual is fitted with the outer hood 1 and the inner hood 2 of Pasternack and the measuring apparatus and delivery lines are arranged. In fact, Burstroem identifies "time consumption" as a disadvantage of the prior art (*see, e.g.,* Burstroem Translation, p. 3) and time savings as an advantage (*see, e.g.,* Burstroem Translation, p. 5).

As a result, the cited references do not support the asserted suggestion/motivation to combine that forms the basis for this obviousness rejection because the rejection fails to provide any reasoning as to why or how one of ordinary skill in the art would modify a qualitative fit testing system such that disclosed in Burstroem with a quantitative system such as that disclosed in Pasternack..

Further evidence of the incompatibility of the systems/methods of the cited references can be found by noting that the systems/methods taught by Pasternack were developed to limit or avoid contamination of the environment around the test apparatus and to use relatively small amounts of test aerosol. *See, e.g.,* Pasternack Translation, pages 3-4. This is in direct conflict with the teachings of Burstroem in which it is expected that the test aerosol (tear gas) will escape into the environment surrounding the test apparatus (tent) during the testing.

In view of the above observations (made with the benefit of the Burstroem translation), Applicants respectfully submit that a proper case of *prima facie* obviousness has not been established because the asserted suggestion/motivation is not supported by the references.

For the above reasons, Applicants submit that the asserted combination of Burstroem and Pasternack do not support a *prima facie* case of obviousness with respect to claims 1-22 and 24-36. Individual sets or groups of claims subject to this rejection are addressed in more detail below.

Claims 4 & 22

With respect to claims 4 & 22 which recite the use of a "set of independent aerosol generators," Applicants note that the basis for this rejection lies in the conclusory assertion that

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the claimed invention involves "the duplication of a known part for a known purpose." Applicants respectfully disagree. As noted above, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-126 (8th Ed., Rev. 1, Feb. 2003) (*citing In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)). Desirability for the asserted modification is not found in the cited references.

In addition, the asserted suggestion/motivation, i.e., "to process more personnel for mask test fit more quickly" is not supported by the cited references. In fact, Burstroem teaches the use of a single source (boiling a tear gas tablet or using a tear gas torch). Use of multiple tear gas sources is not contemplated in the references, nor is there any discussion that using "a set of independent aerosol generators" would enhance testing throughput other than the conjecture of the Examiner.

For the above reasons, Applicants submit that the rejection of claims 4 and 22 does not meet the requirements for a *prima facie* case of obviousness and should be withdrawn.

Claims 6-8 & 38

With respect to claims 6-8 and 38, Applicants submit that the asserted obviousness rejections also do not meet the requirements for a *prima facie* case of obviousness. Method claim 6 recites "delivering a selected amount of the test aerosol to each of the test subjects at predetermined intervals using the aerosol generator system." The citation to Burstroem does not disclose or suggest such a method. Rather, each of the test subjects is exposed to the tear gas in a single dose, not "at predetermined time intervals" as recited in claim 6 (and, thus, claims 7 and 8 which depend from claim 6). This is made clear with reference to the translation provided herewith.

In addition, method claims 8 and 38 recite the delivery of "different selected amounts . . . to at least two of the test stations." The rejection of claim 8 is based on the conclusory assertion that "the suggested device is fully capable of delivering different amounts of aerosol to different

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test stations/subjects." The rejection of claim 38 is based on a similar assertion. As discussed above, however, the asserted "suggested device" is not supported by the references. In addition, with respect to these claims in particular, no suggestion/motivation for performing the claimed methods has been identified as required for a *prima facie* case of obviousness. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-126 (8th Ed., Rev. 1, Feb. 2003) (citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

For the above reasons, Applicants submit that the rejections of claims 6-8 and 38 do not meet the requirements for *prima facie* obviousness and should be withdrawn.

Claims 9 & 28

With respect to claims 9 and 28, Applicants submit that *prima facie* cases of obviousness have not been established. These claims recite "storing the test feedback in a database." The sole basis for the obviousness rejection is that "the suggested device discloses storage of results in a database (See disclosure of element 15 of Pasternack, use/creation of a 'data log')." Applicants disagree.

"Test feedback" is recited in claims 1 and 27 (from which claims 9 and 28 depend, respectively) as being received from a "test subject." Pasternack, however, discloses only a quantitative respirator fit testing method. There is no feedback from a test subject, but only quantitative data based on measurements taken inside the mask. As a result, any assertion that Pasternack discloses "storing the test feedback in a database" in a database is simply not supported by the reference itself.

For the above reasons, Applicants submit that the rejections of claims 9 and 28 do not meet the requirements for a *prima facie* case of obviousness and should be withdrawn.

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Claims 16-20

With respect to claims 16-20, Applicants submit that the rejections and the assertions provided to support them fail to appreciate the full scope of the claimed invention, namely that these claims are directed to methods of delivering a "sensitivity aerosol" in addition to a test aerosol. Some illustrative embodiments of methods that may fall within the scope of claims 16-20 are described in the specification at, e.g., page 12, line 3 to page 13, line 10. Applicants note that the rejections of claims 16-20 do not address the delivery of a "sensitivity aerosol" in addition to a test aerosol as recited in these claims. As a result, no suggestion/motivation for modifying or combining the references to reach the inventions recited in claims 16-20 is provided and a *prima facie* case of obviousness has not been established with respect to these claims.

For the above reasons, Applicants submit that the rejections of claims 16-20 do not meet the requirements for a *prima facie* case of obviousness and should be withdrawn.

Claims 12 & 31

With respect to claims 12 and 31, Applicants note that no discussion as to why or how to combine the cited references to reach the claimed inventions has been provided in support of the rejections of these claims. As a result, Applicants respectfully submit that a proper *prima facie* case of obviousness has not been established with respect to claims 12 and 31.

Claims 26-36

With respect to claims 26-36, Applicants respectfully traverse any assertion that the cited references teach or suggest "remote" administration of fit testing. For a general discussion of remote administration and its potential advantages, the Examiner is direct to page 2, lines 24-31 of the specification. In contrast to remote administration of fit testing, Burstroem clearly requires the test administrator to be at the testing location to, e.g., boil the tear gas pellet. Nor does Pasternack teach remote fit test administration.

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As a result, Applicants submit that a proper case of *prima facie* obviousness with respect to claims 26-36 has not been established and the rejection of claims 26-36 should be withdrawn.

Conclusion

For all of the above reasons, Applicants respectfully submit that the rejections of claims 1-22 and 24-36 do not meet the requirements for proper *prima facie* obviousness.

Reconsideration and withdrawal of the rejections are, therefore, respectfully requested.

Burstroem in view of Pasternack & Tilley

The Examiner rejected claims 12, 31, and 39 under 35 U.S.C. 103(a) as being unpatentable over Burstroem (FOA Report C40208-C1(C2) in view of Pasternack (U.S. Patent No. DE 26 52 136 B1) as applied to claims 1 and 26 above, and further in view of Tilley (U.S. Patent No. 6,435,009). Applicants respectfully disagree.

At the outset, Applicants note that claims 12 and 31 have been amended to recite capture of an image of a test station. As a result, this rejection is rendered moot with respect to claims 12 and 31 because none of the cited references teach or suggest capture of such images.

With respect to claim 39, Applicants note the claimed method includes "capturing at least image of at least one test subject at one of the test stations." Because Tilley does not teach or suggest such a method (capturing screen data is not an image of the test station), Applicants respectfully submit that it cannot (together with Burstroem and Pasternack) form the basis for a proper *prima facie* case of obviousness with respect to claim 39.

Applicants note that this rejection includes assertions that "such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design . . . barring a convincing showing of evidence to the contrary." Applicants respectfully disagree and request that the Examiner provide some factual support that capturing images of a test station or test subject as a part of qualitative fit testing is "old and well known in the art" or a "mere obvious and routine choice of design." See, MPEP §

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2144.03(C), p. 2110-133 (8th Ed., Rev. 1, Feb. 2003). Applicants note that such actions have not been taught or suggested in any of the cited references.

In view of the above, Applicants respectfully submit that claims 12, 31 and 39 are patentable over the combination of Burstroem, Pasternack and Tilley. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Burstroem in view of Pasternack & Loedding et al.

The Examiner rejected claim 23 under 35 U.S.C. §103(a) as being unpatentable over Burstroem (FOA Report C40208-C1(C2) in view of Pasternack (U.S. Patent No. DE 26 52 136 B1) as applied to claim 21 above, and further in view of Loedding et al. (U.S. 5,156,776).

Applicants respectfully disagree.

First, Applicants note that claim 23 depends from claim 22. As discussed above, claim 22 is patentable over the combination of Burstroem and Pasternack. Loedding et al. does not address any of the deficiencies of the rejection of claim 22. For that reason alone, Applicants respectfully submit that claim 23 is patentable over the combination Burstroem, Pasternack and Loedding et al. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

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It is respectfully submitted that the pending claims 1-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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14 JANUARY 2004
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3:57 day of January, 2004, at _____ (Central Time).

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